

Informed Decision-Making for Decentralised Manufacturing of Cell and Gene Therapies

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Regenerative medicine has promised solutions for many of the health issues facing the world's population in the form of tissue engineered products as well as cell and gene therapies CGTs. Current reliance on large cell doses poses sourcing and manufacturing challenges which many research groups and companies are working to overcome.

Despite some successes, key questions remain around the feasibility of manufacturing CaGTs. What scale is appropriate, should we pursue autologous, allogeneic or partially patient matched and how will worldwide healthcare systems reimburse these expensive therapies. Without answers to these critical questions, the stunning breakthroughs we have witnessed will remain isolated examples, unable to be embraced by the wider population.

Decentralised or 'redistributed' manufacturing represents an attractive choice for production of some cell and gene therapies (CGTs), in particular personalised therapies. Decentralised manufacturing splits production into various locations or regions and in doing so, imposes organisational changes on the structure of a company. This confers a significant advantage by democratising supply, creating jobs without geographical restriction to the central hub and allowing a more flexible response to external pressures and demands.

Decentralisation presents unique challenges that need to be addressed including, a reduction in oversight, decision making and control by central management which can be critical in maintaining quality in healthcare product manufacturing. The unwitting adoption of poor business strategies at an early stage in development has the potential to undermine the market success of otherwise promising products. To maximise the probability of realising the benefits that decentralised manufacturing of CGTs has to offer, it is important to examine alternative operational paradigms to learn from their successes and to avoid their failures.

Whilst no other situation is quite the same as CGTs, some illustrative examples of established manufacturing paradigms share a unique attribute with CGTs which aid understanding of how decentralised manufacturing might be implemented for CGTs in a similar manner. We present a collection of paradigms which together represent a roadmap to success for decentralised production of CGTs
